

TITLE OF INVENTION

**Upper Body Convective Heat Therapy Device and Method of Making and Using Same**

CROSS-REFERENCE TO RELATED APPLICATIONS

- 5 [0001] This application is a Continuation of Application Serial Number 09/916,353, filed July 27, 2001.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

- [0002] Not Applicable

10 BACKGROUND OF THE INVENTION

1. Field of Invention

- [0003] This invention relates to the field of heat therapy. More specifically, the present invention relates to a disposable hypothermia article for use with a heat source to supply a source of controlled temperature air to a patient's upper 15 body surface.

2. Description of the Related Art

- [0004] During and after a surgical procedure, it is well known that the loss of body temperature by the patient can lead to hypothermia. Accordingly, it is well known to apply heat to the patient in order to replace the heat that is lost. While 20 heat loss associated with surgery is discussed herein, it is well known that hypothermia is also caused by other circumstances, such as prolonged exposure to extreme cold. No matter what the cause of hypothermia, it is essential to apply heat to the patient in order to either prevent or overcome hypothermia.

- [0005] One method for applying heat to a patient is by directing warm 25 air toward the patient. Of specific interest is a generally U-shaped hollow tubular member through which heated air is supplied. Typical of the art are those devices disclosed is U.S. Letters Patent Nos. 5,165,400, titled "Convective Hyperthermia

Article," issued to Berke on November 24, 1992; and 5,300,101, titled "Method and Apparatus for Treatment of Pediatric Hypothermia," issued to Augustine, et al., on April 5, 1994.

- [0006] The '400 device disclosed by Berke is a U-shaped device having two substantially parallel legs positioned adjacent to and extending a substantial length of a patient's body, and the device directs heated air to the body. The '400 device has a crosspiece connecting the two legs. The '101 device disclosed by Augustine is a device similar to that disclosed in the '400 patent, except that it fits an infant or small child and includes positionable covering sheets.
- 10 [0007] It is an objective of this invention to provide a heat therapy device for a patient who is off-pump. It is a further objective to provide a therapy device for the upper body, specifically the head and upper shoulders.

#### BRIEF SUMMARY OF THE INVENTION

- [0008] According to one embodiment of the present invention, an upper body convective heat therapy device is provided. The heat therapy device is a light weight disposable convective hypothermia article that provides warm air to a patient's upper body. It is suitable for use in off-pump situations; that is, when the patient is not on life-support, but requires a source of heat.
- 20 [0009] In one embodiment, the therapy device is a U-shaped tube that is inflated with a heated air supply. The heated air escapes through slits or an air permeable portion of the tube and is directed towards the patient's head and shoulders. The tube is attached to a flat sheet, upon which the patient lies. Attached to the tube is a flat covering sheet that can be positioned over the patient's upper body without restricting access to the patient. The covering sheet forms a tent over the patient and serves to prevent the heated air from escaping. The covering sheet is fabricated of a clear material that permits viewing the face of the patient.
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- [0010] A method of making the therapy device includes cutting or forming tube sheets, gluing or welding them together, forming exhaust ports in the resulting tube, attaching the tube to a base sheet and a cover sheet. A method for

selectively warming a patient's upper body is disclosed and includes arranging a therapy device around the patient's head and shoulders, forcing heated air into the device, exhausting air from the device and directing the air to the patient. A cover sheet is used to prevent the heated air from immediately escaping.

5                   BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0011]         The above-mentioned features of the invention will become more clearly understood from the following detailed description of the invention read together with the drawings in which:

Figure 1 is a top view of a patient with the therapy device inflated and in place;

Figure 2 is a perspective view of the therapy device;

Figure 3 is a top view of the therapy device;

Figure 4 is a top view of another embodiment of the therapy device;

Figure 5 is an exploded view of the therapy device;

15                 Figure 6 is a perspective view of one panel of one embodiment the device;

Figure 7 is a perspective view of the embodiment illustrated in Figure 6; and

Figure 8 is a flow diagram of the steps for manufacturing one embodiment of the therapy device.

DETAILED DESCRIPTION OF THE INVENTION

20                 [0012]         An apparatus for an upper body convective heat therapy device 10 and a method of making and using the device 10 is disclosed. Referring to Figure 1, the therapy device 10 provides warm air to the upper portion of a patient's body 110. A base sheet 104 is placed under the head and shoulders of the patient 110, who is lying on a table or bed 114. The therapy device 10 is connected to a supply hose 112 from a heated air supply (not illustrated). When air is pumped into the therapy device 10, the tube 102 inflates, and heated air is exhausted in a thermal

warming zone surrounding a portion of the patient's body **110**. A cover sheet **106** prevents the heated air from immediately escaping and is attached **107** to one leg of the tube **102**. The cover sheet **106** is positioned over the head of the patient **110** and placed on top of the tube **102**.

5 [0013] Figure 2 illustrates a perspective view of an inflated therapy device **10**. A first securing strap **206** extending from the seam **222** on the inside of the tube **102** is attached to the base sheet **104**. A second securing strap **306** (not illustrated in Figure 2) extends similarly from the seam opposite that of the first securing strap **206**. The securing straps **206, 306** are attached to the base sheet **104** by any of various methods known by those skilled in the art, including welding, double-sided tape, or hot-glue.

10 [0014] The cover sheet **106** is a clear plastic material that forms a tent over the head of the patient **110** and serves to direct the escaping air over a greater portion of the body of the patient **110** by preventing the immediate escape of the heated air. A portion of one end **107** of the cover sheet **106** is attached **107** to one leg of the tube **102** using means known to those skilled in the art, for example, welding, double-sided tape, or hot-glue.

15 [0015] Also shown in Figure 2 are the exhaust ports or slits **212a, 212b, 212c, 212d** through which the heated air forced into the therapy device **10** escapes. The slits **212** are substantially parallel to a line tangent to the nearest seam edge of the tube **102**. Alternatively, the slits **212** are substantially perpendicular to the tangent of a circumference of the tube **102** defined by a radius perpendicular to the axis of the tube **102**. In another embodiment, the exhaust ports **212** are V-shaped slits; that is, each exhaust port **212** is formed of two slits that are connected at one end and separated at the other end. In still another embodiment, the exhaust ports **212** are holes cut or punched into the tube **102**.

20 [0016] In yet another embodiment, the exhaust ports **212** are an integral part of the fabric of the tube **102**. That is, the tube **102** is fabricated with material that is air impermeable in all areas except where the exhaust ports **212** are located. For example, the tube **102** is fabricated out of air permeable fabric that is

coated with a thin sheet of plastic or other air impermeable material. The coating completely coats the tube **102** material except in the areas in which heated air is to be exhausted. The uncoated areas form the exhaust ports **212** because air escapes from the tube **102** in those areas. Those skilled in the art will recognize  
5 that size, number, and location of the exhaust ports **212** can vary depending on the available air flow without departing from the spirit and scope of the present invention.

[0017] The exhaust ports **212** cover the surface of the tube **102** in the area in which heated air is desired to be exhausted. In the illustrated embodiment, the  
10 tube **102** does not discharge heated air in the area where the patient's ears would be located. The area between exhaust ports **212a** and **212b**, **212c** and **212d** is the area of the tube **102** that is adjacent to the ears of the patient **110**.

[0018] Figure 3 shows a therapy device **10** in a deflated state. The legs **302**,  
15 **304** of the therapy device **10** are splayed out because, when the tube **102** is inflated, the end of the legs **302**, **304** draw towards each other. In the illustrated embodiment, the legs **302**, **304** are substantially parallel to each other when the therapy device **10** is inflated.

[0019] Figure 4 shows another embodiment of a therapy device **10'** in a deflated state. In this embodiment, the legs **402**, **404** of the therapy device **10'**  
20 have a foot-shaped end portion opposite their connection to the crosspiece **308**. The shape of the legs **402**, **404** permits the heated air exhausted from the therapy device **10'** to be directed across the top of the full width of the shoulders of the patient **110**.

[0020] Figure 5 is an exploded view of the therapy device **10**, showing the  
25 base sheet **104**, two tube sheets **502**, **504**, the cover sheet **106**, and the inlet collar **108**. The base sheet **104** is fabricated of the same material as the tube sheets **502**, **504**, although those skilled in the art will recognize that other material can be used without departing from the spirit and scope of the present invention. The cover sheet **106** is fabricated of a thin-gauge clear plastic that is impermeable to  
30 air, for example, 10 gauge clear PVC sheeting.

[0021] The tube **102** is made of two tube sheets **502, 504**, one on top of the other. The tube sheets **502, 504** are fabricated of a material that is not permeable to air, such as a fabric coated with a plastic. Those skilled in the art will recognize that any of various materials can be used without departing from the spirit and scope of the present invention. Common materials include woven and non-woven fabrics and cellulosics. Material that is air permeable can be coated on at least one side with a thin film of plastic or other air impermeable material. The material is waterproof and impermeable to air.

[0022] In the illustrated embodiment, at least one of the tube sheets **502, 504** has two securing straps **206, 306**, each extending from a leg **206, 306** towards the other. In another embodiment, the securing straps **206, 306** are separate pieces of material placed between and secured to the tube sheets **502, 504**. The two tube sheets **504, 504** are sealed together at their common edges **222**. The sheets **502, 504** can be sealed by gluing the opposing surfaces or by welding the plastic coated surfaces. The sealed edge **222** extends into the tube sheet **502, 504** a distance sufficient to provide an air tight seal and provide mechanical strength when the tube **102** is inflated. For fabric with a plastic film, the sealed distance is approximately one-quarter inch.

[0023] In the illustrated embodiment, the tube **102** is secured to the base sheet **104** in four places. The tube **102** is attached by securing the seam **222** on both sides of the inlet collar **108** to the base sheet **104**. The tube **102** can be glued or welded to the base sheet **104**. The tube **102** is secured to the base sheet **104** by the two securing tabs **206, 306** protruding from the tube **102**. Each securing tab **206, 306** is folded under its respective tube leg **302, 304** and secured to the base sheet **104**.

[0024] The inlet collar **108** is secured to the cross-piece of the tube **102**. The inlet collar **108** is a section of stiff material, such as paper or cardboard, with a hole in the center sized to accept the nozzle of the heated air supply hose **112**. The inlet collar **108** is attached to the tube sheets **502, 504** by gluing it to the fabric. Slits **512, 514** are cut into the tube sheets **502, 504** and provide clearance for the nozzle of the heated air supply hose **112**. In the illustrated embodiment, the inlet collar **108** is not secured to the base sheet **104**.

[0025] Figure 6 illustrates a tube sheet **602** for another embodiment of the present invention, which is illustrated in Figure 7. The tube sheet **602**, instead of being laid flat during fabrication, has excess material **604, 606** which is folded over along the length of each leg **302, 304**. After the tube sheet **602** is attached to its mating tube sheet **504**, the tube legs **702, 704** have a greater height than without using the excess material **604, 606**. The excess material **604, 606** at the end of the tube legs **702, 704** can be seen in Figure 7 as a puckered area **712, 714** at the seam **222**. As can be seen in Figure 7, with the upper tube sheet **602** having excess material **604, 606**, the seam **222** on the outside of the tube legs **702, 704** is positioned closer to the base sheet **104** at the end of the tube leg **702, 704** opposite the connection to the crosspiece **708**. In another embodiment, both the top and bottom tube sheets **502, 504** are similar to the tube sheet **602** with excess material **604, 606**. A tube fabricated with excess material **604, 606** on both the top and bottom tube sheet **502, 504** has legs **702, 704** with a greater height, which results in the cover sheet **106** being supported more by the tube legs **702, 704** than the face of the patient **110**.

[0026] Figure 8 is a flow diagram showing the steps of fabricating the therapy device **10**. The first step is to cut the material **802**. Once the material is cut, the tube sheets **502, 504** can be sealed at their common edges **222** by welding **804** or other means for making an air tight seal.

[0027] In the illustrated embodiment, the exhaust ports **212** are slits cut parallel to a tangent line of the tube sheet **502, 504** edge **222**. Once the two tube sheets **502, 504** are fastened together, the exhaust ports **212** are formed **806** by cutting into the material of the tube **102**. The exhaust ports **212** can be cut **806** by lancing slits or punching holes in the tube sheets **502, 504**. In another embodiment, the exhaust ports **212** are uncoated areas of an air permeable material that is partially coated with a thin film of plastic or other air impermeable material. For this embodiment, when the tube sheet **502, 504** material is coated before cutting, the exhaust ports **212** can be formed **806** before the material is cut. Those skilled in the art will recognize that the number of exhaust ports **212** can vary based on their size and the available air supply flow without departing from the spirit and scope of the present invention.

[0028] After the tube sheets **502**, **504** are mated **804**, the tube **102** is secured to the base sheet **104** by attaching the crosspiece **308** of the tube **102** to the base sheet **104** and by attaching the securing straps **206**, **306** to the base sheet **104**. The inlet collar **108** is secured **810** to the tube **102** and the cover sheet **106** is attached **812** to the tube **102**. Lastly, the assembled therapy device is folded and packed **814**, and otherwise made ready for shipment, storage, and use.

[0029] In the illustrated embodiment, the patient **110** is positioned on the base sheet **104** with the head of the patient **110** between the legs **302**, **304** of the therapy device **10**. Heated air is pumped into the therapy device **10** and is exhausted from the exhaust ports **212**, which are of a size and number to maintain a back pressure in the therapy device **10**, which serves to keep the tube **102** inflated. The cover sheet **106** is extended from one tube leg **302**, over the face of the patient **110**, and to the other tube leg **304**. The therapy device **10** disclosed is suitable for use with a patient **110** off-pump.

[0030] From the forgoing description, it will be recognized by those skilled in the art that a therapy device for providing heated air to the upper body of a patient and a method of making the therapy device have been provided. The therapy device is an inflatable U-shaped tube mounted on a base sheet and having a cover sheet. The patient is placed on the base sheet with the patient's head between the legs of the tube. The cover sheet is placed over the patient's face. A heated air supply tube is connected to the tube and the heated air both inflates the tube and is forced out of the exhaust ports of the tube, thereby providing an environment in which a portion of the patient's body is heated.

[0031] While the present invention has been illustrated by description of several embodiments and while the illustrative embodiments have been described in considerable detail, it is not the intention of the applicant to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications will readily appear to those skilled in the art. The invention in its broader aspects is therefore not limited to the specific details, representative apparatus and methods, and illustrative examples shown and described. Accordingly, departures may be made from such details without departing from the spirit or scope of applicant's general inventive concept.